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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,048	08/10/2001	Thomas L. Cantor		7860

7590 10/21/2003
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EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 10/21/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/928,048

Applicant(s)

CANTOR, THOMAS L.

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 12-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-11 and 17-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II claims 7-11, 17 and 18 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the subject matter of claims 1 (Group I) and 7 (Group II) are related as combination and subcombination. This is not found persuasive because of reasons set forth in the previous office action and further because Groups I and II are not related as combination and subcombination. The two methods are directed to the measurement of different proteins. The method of Group I is a method for determining cyclase inhibiting parathyroid hormone (CIP) whereas Group II is a method for measuring the amount of cyclase inhibiting parathyroid hormone (CIP) fragment. Therefore, the two methods are distinct and independent. Applicant further argues that undue search burden does not appear to be present because the field of search of Group II would include a search of the elements of claim 1 (Group I). Literature searches for each method is distinct since the protein structures of each invention are different. While searches would be expected to overlap, there is no reason to expect the searches to be coextensive.

The requirement is still deemed proper and is therefore made FINAL.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e.,

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continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

In the instant case, the application claims benefit of 60/224,447 filed 08/10/200.

However, the provisional application is not referenced in the first sentence of the specification.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 7-11 and 17-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. On page 4, third paragraph, lines 23-28 in the specification. The applicant discloses that the present invention incorporates a discovery that a large, non-whole PTH peptide fragment, a peptide having an amino acid sequence from between (SEQ ID No. 4[PTH₂₋₈₄]) and SEQ ID No. 5 [PTH 34-84]), functions in vivo as an antagonist of CAP. In other words, the bind of CAP to PTH receptors and the subsequent biological activity are affected by the presence of this cyclase inhibiting PTH peptide fragment. The applicant does not

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disclose what this CIP fragment is. There is no description in the specification disclosing what the CIP fragment actually is.

4. Claims 7-11 and 17-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. The factors that must be considered in determining undue experimentation are set forth in *In re Wands* USPTQ2d 14000. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The instant claims are directed to a method for measuring the amount of cyclase inhibiting parathyroid hormone (CIP) fragment in a sample by adding to the sample a first antibody or antibody fragment specific for a peptide sequence for cyclase inhibiting parathyroid hormone (CIP), but does not bind to this same peptide sequence in cyclase activating parathyroid hormone, in an amount sufficient to bind the CIP present and allowing the first antibody to bind to any CIP present, thereby forming a complex that specifically binds to a portion of CIP other than the initial peptide sequence which binds

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to the first antibody and allowing the second antibody to bind to the complex wherein the first antibody or the second antibody has a label or signal generating component attached thereto; and measuring the amount of labeled complex.

The disclosure fails to teach what the cyclase inhibiting parathyroid hormone fragment is. The specification on page 4, third paragraph, lines 23-28 disclose that a large, non-whole PTH peptide fragment, a peptide having an amino acid sequence from between (SEQ ID No. 4 [PTH₂₋₈₄]) and (SEQ ID No. 5 [PTH₃₄₋₈₄]), functions in vivo as an antagonist of CAP. In other words, the binding of CAP to PTH receptors and the subsequent biological activity are affected by the presence of this cyclase inhibiting PTH peptide fragment, referred to herein as CIP. However, it is not disclosed in the specification what the fragment is.

Because the disclosure fails to teach what the fragment is, one of ordinary skill in the art would not be able to generate an antibody for the fragment without undue experimentation and thus one would have a low level of predictability in the art. Further, there are no working examples provided in the specification to provide guidance.

Therefore, such is not seen as sufficient to support the breadth of the claims and one skilled in the art cannot practice the claimed invention without undue experimentation, because if one does not know what the cyclase inhibiting parathyroid hormone (CIP) fragment is, then one of ordinary skill in the art could not generate an antibody for the peptide sequence in CIP without undue experimentation.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 7-11 and 17-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7, part (a) the recitation "sufficient" is vague and indefinite. The term sufficient is a relative term, which renders the claim indefinite. There is no definition or guidance provided for the term in the specification.

Claim 10 "the mid-portion of CIP" there is insufficient antecedent basis for this limitation.

Claim 10 "the C-terminal of CIP" there is insufficient antecedent basis for this limitation.

Claim 10 "an epitope left open after CIP binds to the first antibody and the second antibody, thereby forming a precipitating mass" is vague and indefinite. It is unclear what applicant intends.

Claim 11 the C-terminal CIP antibody" there is insufficient antecedent basis for the limitation.

Claim 17 "substantially" is vague and indefinite. The term "substantially" is a relative term which renders the claim indefinite. There is no definition or guidance provided for the term in the specification.

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Claim 18 "the C-terminal portion of CIP" there is insufficient antecedent basis for this limitation.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gary W. Counts
Examiner
Art Unit 1641
October 20, 2003



LONG V. LE
SUPERVISORY PATENT EXAMINER
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10/20/03